

25062. Misbranding of Lydia E. Pinkham's Tablets. U. S. v. 84 Packages of Lydia E. Pinkham's Tablets, and two other libels against the same product. Default decree of condemnation, forfeiture, and destruction in each case. (F. & D. nos. 30578, 30579, 30580. Sample nos. 31899-A, 31900-A, 42901-A, 42902-A.)

Examination of the drug preparation, Lydia E. Pinkham's Tablets, disclosed that the article contained no ingredient or combination of ingredients capable of producing the curative or therapeutic effects claimed for it in statements borne on the carton and bottle label of the product and in a circular that accompanied shipments of it. The bottle label bore the statement in part: "For functional ailments of women such as irregular or suppressed menstruation, excessive menstruation, painful menstruation."

On June 10, 1933, the United States attorney for the Southern District of New York, acting upon reports by the Secretary of Agriculture, filed in the district court libels praying seizure and condemnation of 142½ packages of Lydia E. Pinkham's Tablets, alleging that the article had been shipped in interstate commerce on or about various dates in the period from March 20, 1933, to May 24, 1933, by the Lydia E. Pinkham Medical Co., from Lynn, Mass., into New York, N. Y., and charging misbranding in violation of the Food and Drugs Act.

It was alleged in each of the libels that the article was misbranded in that the following statements regarding the curative or therapeutic effects of the article were false and fraudulent: (Carton and bottle label) "For functional ailments of women such as irregular or suppressed menstruation, excessive menstruation, painful menstruation"; (circular) "Amenorrhea (Irregularity or absence of the menstrual flow) Functional or secondary amenorrhea is the name given to those cases in which the patient with normal generative organs and in average health, ceases to menstruate without any apparent objective cause, local or constitutional. This condition may be caused by sudden excitement, mental shock or fright, by change of climate or occupation; by overstudy or nervous exhaustion; also by taking cold or getting the feet wet during the menstrual period. Treatment: In cases of functional amenorrhea take Lydia E. Pinkham's Tablets according to directions, and continue until relief is obtained. They are indicated when the menstrual function fails to appear, or later when there is irregularity or absence of the menstrual flow. In some cases, relief may be obtained by taking two to four tablets every three or four hours, two or three days before the expected sickness. The young girl entering womanhood (usually from her twelfth to her fifteenth year) * * * In cases of prolonged amenorrhea it may be best to take her out of school for a while. Give strict attention to keeping the bowels open as constipation is closely associated with amenorrhea. * * * Primary amenorrhea may be caused by imperfect development; constitutional disturbances such as chlorosis, tuberculosis, diabetes, inflammation of the kidneys, syphilis, etc.; defective ovarian action. In cases where primary amenorrhea is indicated, consult your doctor. Essential Dysmenorrhea (Painful Menstruation) This is characterized by severe cramp-like pains in the lower abdomen at the time of menstruation. The patient is entirely free from pain between periods. At the menstrual period, just before or at the appearance of blood, the patient is seized with severe cramp-like pains in the lower abdomen which extend into the back or down the legs, lasting from a few hours to one or two days. Severe headache and a feeling of uneasiness or general discomfort are often present. Vomiting is not uncommon. Treatment: Take Lydia E. Pinkham's Tablets according to directions, and continue the treatment for a time, that you may obtain permanent relief. In some cases the pain and discomfort may be avoided by taking two to four tablets every three or four hours, two or three days before the expected period and continuing until it is over. In cases of severe pain favorable results are often obtained by taking the tablets with warm tea. In all cases of dysmenorrhea give close attention to the general health. * * * Keep the bowels open, for painful menstruation is often associated with constipation. * * * A careful observance of these rules, in conjunction with these tablets, should rapidly relieve the pain and discomfort, and the patient, after a while, can resume her regular habits during such times. Menorrhagia (Excessive Menstruation) Excessive menstruation may consist of an increased amount of blood at the usual menstrual period, or a prolongation of the period, or its too frequent recurrence. It is believed to be caused by a disturbance of the internal secretion of the ovaries or of other internal secretory glands. It may also be caused by defective muscles of the uterus or

changes of the circulatory apparatus. There is no doubt that a loss of tone in the muscles of the uterus, with consequent insufficiency of uterine contraction plays an important role in these cases. Treatment: Take Lydia E. Pinkham's Tablets as directed and continue the treatment for some time. If you have reason to suspect a uterine tumor in connection with Menorrhagia, consult your Doctor. General Rundown Condition, Nervousness and Irritability. Women are often subject to a general physical upset by lack of function of the generative organs. Especially is this so regarding the ovaries, and any lack of function of these glands results in a general upset of the other organs of the body. Some of the common symptoms are: Nervousness, tired feelings, headaches, dizziness, achy feelings in various parts of the body, irritability, excitability, sleeplessness, poor appetite and 'blue' spells. There is usually a feeling of lassitude resulting in the patient being forced to stop even her ordinary occupation, or duties owing to this feeling of exhaustion. This may be associated with headache or a feeling of pressure in the head, pains in the back and sleeplessness. The digestion is often upset, certain foods causing a heavy feeling, general soreness in the abdomen, gas and nausea. Treatment: Take Lydia E. Pinkham's Tablets as directed and continue the treatment for some time. A glass of warm milk or malted milk taken with the tablets upon retiring will promote a favorable effect."

An answer by the Lydia E. Pinkham Medical Co., denying all material allegations of the libel was made in each case. Motions by the company to adjourn the trial of the cases beyond the June Term 1935 were denied. Motion in each case for leave to withdraw the answer therein was granted.

On August 10, 1935, default in answering existing in each case, a decree of condemnation, forfeiture, and destruction, and for costs was entered in each.

W. R. GREGG, *Acting Secretary of Agriculture.*

25063. Misbranding of Hinkle's Kidney And Bladder Capsules. U. S. v. Leon Evans, trading as the Hinkle Capsule Co. Plea of guilty. Fine, \$25. (F. & D. no. 31356. Sample no. 34271-A.)

The label on the packages of this article bore, and a circular enclosed in the packages contained, unwarranted curative and therapeutic claims.

On July 9, 1934, the United States attorney for the Western District of Kentucky, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Leon Evans, trading as the Hinkle Capsule Co., Mayfield, Ky., alleging shipment by said defendant, in violation of the Food and Drugs Act, on or about November 14, 1932, from Mayfield, Ky., to Cairo, Ill., a number of packages of Hinkle's Kidney and Bladder Capsules which were misbranded. The article was labeled in part: (Packages) "Hinkle's Kidney and Bladder Capsules Hinkle Medical Co., Inc., Mayfield, Kentucky."

Analysis showed that the article consisted essentially of powdered cubeb and santal oil with small proportions of iron, calcium, magnesium, sodium, and potassium compounds.

It was charged that the drug was misbranded in that the packages and boxes and a circular enclosed in the packages bore and contained false and fraudulent statements that the article was effective, among other things, as a treatment, remedy, and cure for kidney and bladder troubles; effective as a preventive of getting up at nights; effective as a preventive of diabetes, Bright's disease, and many other serious renal ailments; effective to promote and maintain a sanitary condition of the kidneys and bladder and to assist nature in restoring normal action by making the kidneys and bladder sound and healthy and able to resist disease; and effective to insure healthy kidneys and bladder.

On April 15, 1935, a plea of guilty was entered and a fine of \$25 imposed.

W. R. GREGG, *Acting Secretary of Agriculture.*

25064. Adulteration of (1) Fluid Ex. Stramonium; (2) Sol Ammonium Acetate (Spirit of Mindererus); (3) No. 638 Spirit Nitrous Ether; (4) Spirit Ammonia Arom.; (5) Syrup Hydriodic Acid; (6) Tincture Cinchona Compound; (7) No. 187 Elixir Glycerophosphates Compound; (8) Compressed Tablets 500 No. 1050 Aikens Tonic; (9) Fluid Extract Belladonna Leaves; (10) Fluid Extract Belladonna Root; (11) Fluid Extract Hyoseyamus. U. S. v. Sutliff & Case Co., Inc., a corporation. Plea of guilty. Fine, \$385 and costs. (F. & D. no. 31422. Sample nos. 17021-A, 17024-A, 17030-A, 17113-A, 17115-A, 17116-A, 17121-A, 25505-A, 25510-A, 25511-A, 25513-A.)

This case was based on shipments of various drugs each of which, in one or more respects, failed to conform to the requirements of the Food and Drugs